K063434

JAN 2 2 2007

LINDE MEDICAL SENSORS AG

RADIOMETER COPENHAGEN

510(k) Summary

Submitted by: Radiometer Basel AG
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Date Summary prepared: October 30, 2006

Trade Name: TOSCA 500 $tcPCO_2$, SpO_2 and Pulse Rate Monitoring System

Common Name: Cutaneous Gas Monitor / Pulse Oximeter

Classification Name: Monitor Carbon Dioxide Cutaneous (73LKD) / Oximeter (74DQA)

Substantially Equivalent Device: TOSCA 500 $tcPCO_2$, SpO_2 and Pulse Rate Monitoring System
510(k) Number: K043357

Description of the TOSCA 500 $tcPCO_2$, SpO_2 and Pulse Rate Monitoring System

The TOSCA 500 Monitoring System is designed for the simultaneous continous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate, using a single sensor (TOSCA Sensor).

The system consists of a TOSCA Monitor equipped with an integrated calibration unit which allows a fully automatic calibration of the PCO_2 part of the sensor and also provides a storage facility for the sensor, and with the Masimo SET signal extraction technology for the calculation of the functional oxygen saturation and the pulse rate ; a TOSCA Sensor comprising the elements of an electrochemical Stow-Severinghaus-type carbon dioxide sensor and of an optical pulse oximetry sensor; supplies for the sensor preparation; supplies for the sensor attachment to the patient, and a gas mixture for the sensor calibration.

With the new TOSCA Fixation Rings 32mm (subject of this new 510(k)), the TOSCA sensor may be battached to the forehead or the cheek, and to other conventional mesuring sites for tcPCO2 measurement only.

Intended Use

The TOSCA 500 Monitoring System is designed for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate in adults and pediatrics.

Principles of Operation

The TOSCA 500 System is used for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate, using a single sensor (TOSCA Sensor) applied to the ear lobe, the forehead, the cheek or other measuring sites for tcPCO2 measurement only.

Transcutaneous measurement of PCO_2 makes use of the fact that carbon dioxide gas is able to diffuse through body tissue and skin and can be detected by a sensor at the skin surface. By warming up the sensor, a local hyperemia is induced, which increases the supply of arterial blood to the dermal capillary bed below the sensor.The PCO_2 part of the TOSCA sensor consists of a Stow-Severinghaus type electrode. PCO_2 is measured by determining the pH of an electrolyte solution. A change in pH is proportional to the logarithm of the PCO_2 change. The pH is determined by measuring the potential between a miniaturized glass pH electrode and an Ag/AgCl reference electrode. The electrolyte is provided within a thin hydrophilic spacer, which is placed over the sensor surface and is coupled to the skin via a highly gas permeable hydrophobic membrane. The sensor is calibrated in a gas of a known CO_2 concentration. The slope (change of potential with PCO_2) is preset in the sensor memory.

The principle of the SpO_2 measurement is based on the difference in the light absorption characteristics of haemoglobin in its oxygenated and reduced forms. The SpO_2 part of the TOSCA sensor consists of two light emitting diodes, a red (660 nm) and an infrared (880 nm), and a photodiode. The light originating from the diodes passes through the capillary bed and is redirected to the photo-detector by a light reflecting material (attachment clip or ring at the ear lobe) or by an underlying bone (at the forehead or cheek). The light received by the photo detector is converted to electrical signals which are analyzed by the monitor. The signals containing pulsatile components which are caused by variations in blood volume synchronous with cardiac action reflecting inflowing arterial blood and fluctuating absorbance of venous blood due to patient motion are analysed with the Masimo SET Signal Extraction Technology incorporated in the TOSCA 500 Monitor. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET signal processing decomposes the red and infrared pulsatile absorbance signals into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation in the Masimo Set software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states.

Environmental Testing

Applicable environmental, electrical, EMC and mechanical Testing per Reviewers Guidance for Premarket Submissions – November 1993 were performed and the TOSCA 500 Monitoring System passed all tests.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (24 hours to 30 days) as defined in ISO-10993-1:1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests. All patient contacting material passed.

Non clinical tests performed that support a determination of substantial equivalence

The TOSCA Monitoring System, with the TOSCA Sensor applied to the forehead and to the cheek with the new TOSCA Fixation Rings was subjected to testing in house on adults volunteers. The tcPCO2 values measured with the TOSCA System at the forehead and at the cheek using the new TOSCA Fixation Rings were compared to the values measured at the ear lobe using an Attachment Clip (validated with the predicate device by comparison with arterial blood gas values). The results show that a good correlation exists between the values measured at the forehead and at the cheek and the values measured at the ear lobe.

Clinical tests performed that support a determination of substantial equivalence

Clinical studies using the TOSCA Monitoring System, with the TOSCA Sensor applied to the forehead and to the cheek with the new TOSCA Fixation Rings, were performed on healthy adults volunteers subjected to induced hypoxia.

The arterial hemoglobin saturation values measured with the TOSCA System were compared to the values determined from arterial blood samplings with a co-oximeter. The results show that the TOSCA System performs as intended and that the specified saturation accuracy is met.

The Pulse Rate values measured with the TOSCA System at the forehead and at the cheek were compared to the values measured at the ear lobe using an Attachment Clip (validated with the predicate device by comparison with the heart rate obtained by ECG). The results show that the TOSCA System performs as intended and that the specified Pulse Rate accuracy is met.

Conclusion

The results of the environmental, bench and clinical testing demonstrate that the TOSCA 500 $tcPCO_2$, SpO_2 and Pulse Rate Monitoring System and accessories are safe, effective and performs as well as the predicated device.

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SWITZERLAND

JAN 2 2 2007

Re: K063434
Trade/Device Name: TOSCA 500 $tcPCO_2$, SpO_2 and Pulse Rate Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ and LKD
Dated: November 8, 2006
Received: November 13, 2006

Dear Mr. Palma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

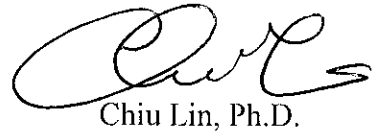
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
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Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **TOSCA 500 $tcPCO_2$, SpO_2 and Pulse Rate Monitoring System**

Indications For Use:

The TOSCA 500 Monitoring System is designed for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and Pulse Rate in adults and pediatrics.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Anesthesiology, General Hospital,
[illegible] Control, Dental Devices

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